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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,956	07/09/2001	John N. Feder	8907-091-999	8853

7590 03/25/2003

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EXAMINER
GUPTA, ANISH

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,956	FEDER ET AL	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s) _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The preliminary amendment filed 12-10-01 is acknowledged. Claims 1-13 were canceled by the amendment and claims 14-19 were added. Claims 14-19 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention are drawn method of inhibiting TfR binding to transferrin or method of treating iron overload disease using polypeptide.

(2) The state of the prior art

The art does not recognize the ability of peptides, similar to those claimed, that inhibit TfR binding to transferrin or method of treating iron overload disease.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

As with all peptides in peptide chemistry, the activity of a peptide is dependant upon its structure and its ability to fold properly. It is known in the art that computer models assist in the research, however they are not are not an absolute prediction tool for the activity of the compound. For example, in peptide chemistry Ngo et al. teach that for proteins and peptides, a " 'Direct' approach to structure prediction, that of directly simulating the folding process, is not yet possible because contemporary hardware falls eight to nine orders of magnitude short of the task." (see page 493 in Ngo et al.) Accordingly, it is not known if an efficient algorithm for predicting the structure exist for a protein or peptide from its amino acid alone (see page 492 in Ngo et al.). Similarly the Science article also states that although computers can be used to design drugs, "for the most part technicians must still screen many, many compounds to find their magic bullets." (see page 441). The article concludes that computer models are not an effective method of determining drug activity. "Even modest gains in the ability to predict drug activity from structural data will be enough to delight some computational biologist. 'Developing drugs is a vague science in which you synthesize a large number of compound." (See page 441).

(5) The breadth of the claims

The claims are extremely broad. The claims define a single amino acid in a 17 amino acid peptide. The rest of the amino acids are have a genus that are hydrophobic, acid, basic apolar etc... Given that sixteen of the seventeen amino acids are undefined, the number within the overall genus is extremely large.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples

The specification states that the peptide binds to the transferrin receptor and this, in turn, lowers TfR affinity for the transferrin, the major iron binding protein found in the serum (see page 1 in the specification). The amount of guidance given is in the form of a single sequence, SEQ ID. NO. 1, to demonstrate the desired activity. This peptide corresponds to the native fragment in the HFE protein. The specification does not provide any examples that would demonstrate any conservatively substituted peptide, including substitution with a non-naturally occurring amino acid, would have the same receptor recognition and binding activity as the native peptide. Applicants entire conclusion is based on a premise that since conservative amino acids are involved, the claimed peptides would have the same activity as the native. As stated above, the activity of the compounds is solely based on the data obtained from computer models. As stated above, the art is skeptical of associating activity for a peptide based on structure alone. Both Rudinger et al. and Ngo et al. indicate that computation hardware and general knowledge of peptide chemistry fail to provide guidance as to the activity of any given peptide. The art also indicates that computer models are also insufficient to provide guidance and give a prediction of activity. Although computers can be used to design drugs, "for the most part technicians must still screen many, many

compounds to find their magic bullets." (see page 441). The article concludes that computer models are not an effective method of determining drug activity. "Even modest gains in the ability to predict drug activity from structural data will be enough to delight some computational biologist. 'Developing drugs is a vague science in which you synthesize a large number of compound." (See page 441). Moreover it is stated computers are unable at this point to design a drug from scratch (see page 441). These articles make these conclusions for any compound regardless of conservative or non-conservative substitutions. Although working examples are not required, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases."

(8) The quantity of experimentation necessary

Since, the is uncertain to predict the different aspects of biological activity, one of ordinary skill in the art would be burdened with undue painstaking experimentation study to determine if the compounds of the claimed invention would contain be active as claimed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

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